

REMARKS/ARGUMENTS

The Status of the Claims

Claims 1-131 are pending with entry of this amendment, claims 1-39 and 127-129 being elected with traverse. Claims 18, 41, 42, 67, 99, and 117 are amended herein. These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record. Support for the amendments is replete throughout the specification; for example, see specification at paragraphs [0059], [0068] and [0089].

Applicants submit that no new matter has been added to the application by way of the above Amendment. Accordingly, entry of the Amendment is respectfully requested.

Restriction Requirement

Applicants respectfully request that the claims of Group 1 (claims 1-39 and 127-129), Group IV (claims 50-55 and 130), Group VI (claims 64-73) be rejoined and considered by the Examiner. The method claims of these three groups involve a) contacting the dimer/heterodimer regulatory site (DHRS) of a nuclear receptor with an agent and b) detecting an effect (e.g., a change in dimer formation or cofactor interaction, a specific binding, a modulatory activity). All three of these groups are classified in the same class (class 435, Chemistry: Molecular Biology and Microbiology) and subclass 7.1+ (involving antigen-antibody binding, specific binding protein assay or specific ligand-receptor binding assay). Applicants respectfully submit that these claims do not present independent and distinct inventions, as described under 35 U.S.C. §121 and 37 CFR §§ 1.141 and 1.142, nor do they present an undue burden on the examination of the application. Applicants respectfully request that the claims be rejoined prior to examination

Applicants also submit that the “further restriction” portion of the requirement is improper and respectfully request that it be withdrawn. The Courts have made it absolutely express and unequivocal that **the Patent Office flatly lacks the statutory authority to impose such a rejection**, whether in the context of a restriction requirement, or otherwise. Should the Office withdraw this improper restriction of the claimed invention and instead request an election of species for initial examination, Applicants elect “steroid hormone receptors” as the species of nuclear receptor.

A. 35 USC § 121 DOES NOT PROVIDE A BASIS TO REJECT A CLAIM FOR MISJOINDER OR LACK OF UNITY

Applicants note that all case law addressing the issue of restricting embodiments of a claim away from the claim, as the Rejection plainly requires for the claims, is perfectly express that the

Office **flatly lacks the authority to use 35 USC § 121 as a basis for forcing amendment of a claim.**

The Courts have repeatedly stated that the divisional statute provides no basis at all for the separation of claim elements within a single claim, as the Office has here required. That is, the Action requires restriction to a single specific nuclear receptor for each group of claims, even though the independent claims in the relevant groups are generic to all such possible receptors. This is flatly improper. As the Courts have noted:

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification. *See, In Re Weber, Soder and Boksay* 198 USPQ 328, 331 (C.C.P.A. 1978). *See also, In Re Haas* 179 USPQ 623, 624, 625 (*In Re Haas I*) (C.C.P.A. 1973) and *In Re Haas* 198 USPQ 334-337 (*In Re Haas II*) (C.C.P.A. 1978).

It has, thus, long been held that **the Office simply may not restrict a particular claim on the basis that it claims independent and distinct inventions.** *See, In Re Weber, Soder and Boksay, supra.* The courts have ruled that, without exception, the statute authorizing restriction practice, i.e., 35 U.S.C. §121, simply provides no legal authority whatsoever to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See, In Re Weber, Soder and Boksay, In Re Haas I* and *In Re Haas II*. In the cases set forth above, the courts expressly ruled that there is simply no statutory basis at all for rejecting a claim for "misjoinder" (inclusion of multiple independent inventions within a claim) despite previous attempts by the Patent Office to fashion such a rejection. For example, *In re Webber* (198 USPQ 328) sets forth the following (*see*, 331-332):

"It is apparent that §121 provides the commissioner with the authority to promulgate rules designed to restrict an application to one of several claimed inventions when those inventions are found to be "independent and distinct." It does not, however, provide a basis for an examiner, acting under the authority of the commissioner to reject a particular claim on the same basis."

In re Haas (198 USPQ 335) interprets this as a *per se* holding, in the very next case by the court:

"In *In re Weber*... decided of even date, this court holds that § 121 does not provide a basis for rejection of a claim. To the extent that § 121 was employed as a basis for rejection, that rejection is, on the authority of *Weber*, reversed."

As the Court has also noted:

"The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-- no matter how broad, which means no matter how many independently patentable inventions may fall within it." *See, In Re Weber, Soder and Boksay* at 334.

As the Courts have repeatedly-- and pointedly-- indicated, the Office simply may not refuse to examine a claim, no matter how many inventions it embraces.

B. SPECIAL CONSIDERATIONS REGARDING UNITY OF INVENTION

The groups at issue comprise Markush-style dependent claims directed to various embodiments of nuclear receptor being modulated in the claimed methods of screening, which appears to be the basis for the "further restriction" portion of the rejection. Because the MPEP seems at first glance to consider restriction practice of Markush style claims with respect to Unity of Invention (MPEP 803.02), a great deal of confusion has, unfortunately, become commonplace in the Office as to appropriate restriction practice when considering questions of restriction practice for Markush style claims. It is instructive to consider how this section arose in the MPEP to understand what the law is and what it is not when performing this analysis.

After the *Weber* decision, noted above, a previous version of 803.02 that purported to fashion a rejection for "misjoinder" of a Markush-style claim was actually *cancelled out of the MPEP*. That is, for a time, the section corresponding to MPEP 803.02 simply stated:

the subject matter formerly under this subtitle has been cancelled in view of the decisions *In Re Weber et al.* 198 USPQ 328 (CCPA 1978) and *In Re Haas* 198 USPQ 334 (CCPA 1978).

This is further evidence of the absolute and per se nature of the holdings of *Weber* and *Haas* with respect to misjoinder-style restriction requirements—it was plainly well understood that *Weber* and *Haas* categorically and unequivocally forbade the Office from making such restriction rejections. In 1980, the Courts again considered the issue of "misjoinder" in the seminal case of *In Re Harnisch* 206 USPQ2d 1059, which considered whether there was a non-statutory basis for a rejection for lack of unity

that was entirely distinct from restriction practice authorized by 35 USC § 121. The *Harnisch* Court was plainly concerned that the two issues would be confused, noting that:

It should be clear from what we have said that we adhere to our holdings in *In re Weber*, supra and *In Re Haas* (Haas II), supra. Nothing we have said herein is intended to change or modify them in any way; nor do we think anything said could be construed to have such an effect. The “unity of invention” concept is not to be confused with the “misjoinder” under 35 USC 121 rejection employed in *In re Weber*. In *Weber*, we dealt with the use of 35 USC 121, which deals only with restriction requirements, to support the rejection of a single claim. Here we are concerned only with the rejection of a single claim on the distinct ground that it is directed to an improper Markush group.”

The Court’s concern that the Patent Office would confuse the issues of divisional practice under 35 USC § 121 and unity of invention practice has, unfortunately, proven to be well founded. In reinstating MPEP § 803.02, the organizers of the MPEP addressed *Harnisch* (it is the Court decision that now underlies the section), but awkwardly left the original previously cancelled headings for the section in place, seeming to suggest that the issue is really one of restriction practice. As the Court plainly and expressly made clear (*see above*), it is not.

Indeed, as the *Harnisch* court made as clear as humanly possible, the issue when considering “improper Markush” is not an issue of restriction practice at all. Instead, the as the court bluntly stated above, the possibility that a Markush-style claim may lack of unity of invention, is a “*distinct ground*” of rejection. As the Court clearly indicated, this issue simply has nothing at all to do with restriction practice. *Id.* As *Harnisch* makes entirely clear, **improper Markush is flatly not a basis for imposing a restriction requirement at all.**

Indeed, even the Board decision that the *Harnisch* case was an appeal from had previously reversed the improper Markush rejection by the Examiner, which had been based upon 35 USC § 121 (*Haas* and *Weber*, discussed above, plainly required this result), and fashioned a *different* “improper Markush” rejection based upon unity of invention, an issue gleaned not from statute, but from consideration of judicial precedents (*Harnisch* at 304-305). The Court acknowledged the possibility of such a “unity of invention” style improper Markush rejection under various court precedent (but *not* under any statute and, as specifically noted, ***not under 35 USC §121!***), but found that a rejection was proper *only* where the members of the Markush group were “truly independent *and* distinct.” *Id.* at 306, *emphasis in the original*. The Court made quite plain that this was a high hurdle and that the Office had *not* shown a lack of unity in the relevant case, because the subject Markush members at issue could be classified together in a manner that was not “repugnant to scientific coclassification.” *Id.* at 305.

Accordingly, even if “unity of invention” cannot be found amongst the members of a Markush, 35 USC § 121 *still* does not provide a basis for *restriction* as the Office has done in the present case. As the noted above, *there is simply no such thing as a rejection for misjoinder and, accordingly, rather than restricting elements of a claim away from themselves (the per se definition of misjoinder), the only option open to the Office when attempting to make a rejection for lack of unity of invention is to attempt to make a rejection for improper Markush.* As the Courts have definitively ruled, the Office flatly lacks the statutory authority to fashion such a rejection pursuant to *restriction* practice, i.e., **there is no such thing as a rejection for misjoinder**. There is absolutely no exception to this *per se* rule. The Courts have repeatedly noted the *per se* nature of this rule, as noted above. The Courts have never held otherwise.

In summary, it is clear that the Action completely confuses the concepts of restriction practice and improper Markush and, in addition, does *not* establish the requisites for either. In the case underlying MPEP 803.02, i.e., *In Re Harnisch*, the Court strongly reiterated that the divisional statute **does not provide the basis for a rejection of the claims**, even in the context of a Markush-style claim. *In Re Harnisch* 206 USPQ2d 300, see, e.g., headnote 6 and page 305. As clearly articulated by the *Harnisch* Court, the *only* procedure available to the Office if unity of invention is lacking is to reject the claim for improper Markush on that basis—an event that takes place not under the auspices of divisional practice articulated by 35 USC 121, or, indeed, as the *Harnisch* Court clearly articulated, *any* statutory section, but under judicially recognized precedent with respect to “unity of invention.” The hurdle in making such a unity rejection is high, i.e., that the members of the Markush group must be “truly independent *and* distinct” (emphasis in the original) or, as the Court stated another way “repugnant to scientific classification.” This obviously cannot be established in the present case. Nuclear receptors are, by definition, an art-recognized co-classified set of molecules and there is every reason to expect that Applicants’ invention is equally applicable to all of them. Thus, there is no basis at all in the subject case for making an improper Markush rejection, any more than there is a basis for restriction of individual components of a claim away from themselves (misjoinder).

REQUEST FOR EXAMINER INTERVIEW

For the reasons noted above, the further restriction requirement must be withdrawn. Applicants have also proposed an alternate grouping of claims (groups I, IV and VI) that is entirely reasonable with respect to examination burden in the subject case. In the event that the claims of groups I, IV and VI are rejoined, Applicants respectfully elect the rejoined group and request to proceed with examination of "steroid hormone receptors" as the species for initial examination..

In the event that the restriction is maintained in its current form, **Applicants hereby request an interview with the Examiner and the Examiner's SPE to discuss the subject restriction requirement PRIOR TO ANY ACTION ON THE MERITS.**

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Respectfully submitted,



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Attachments:

- 1) A petition to extend the period of response for **four** months;
- 2) A transmittal sheet;
- 3) A fee transmittal sheet; and,
- 4) A receipt indication postcard.